Funding Opportunity Announcement (FOA) PS08-802 HIV/AIDS Surveillance: Enhancing Laboratory Reporting
Massachusetts Department of Public Health

Need

In order to meet the goals of preventing new HIV infections, providing care and support services for persons living with HIV/AIDS, and ensuring an equitable resource base for public health and medical/social services, a complete, population-based HIV/AIDS surveillance system remains a high priority for the Commonwealth of Massachusetts. As incident and prevalence cases of HIV/AIDS increasingly occur among disenfranchised populations, including the poor, racial and ethnic minorities, the mentally ill, and newly arrived immigrants and refugees, standard case reporting based on clinical encounters with reporting providers risks missing cases of HIV disease among individuals inconsistently in care. Further, the implementation of names-based HIV reporting in 2007, replacing the former system based on a unique identifier (UI) has created a situation where name ascertainment of a significant number of individuals previously reported by UI remains incomplete.

In order to better identify for epidemiologic follow-up and recording those individuals never previously reported or only reported by UI, supplemental laboratory indicators of potential HIV infection must be collected on a routine basis. Currently in Massachusetts, only CD4+ T-lymphocyte tests revealing counts below 200 cells/ml are required to be reported under state HIV/AIDS surveillance regulations, and reporting of HIV viral load test results are not currently required under state public health regulations. While an extensive and efficient electronic laboratory reporting (ELR) system is currently in place to receive a broad range of laboratory indicators of infectious disease, neither full-range CD4+ T-lymphocyte test results nor HIV viral load detection test results can be accommodated by the Massachusetts Department of Public Health's (MDPH) existing surveillance information system. New regulatory requirements and additional information system capacity is needed to achieve the goal of a maximally complete, population-based HIV/AIDS surveillance system.

Plan

MDPH plans to utilize these supplemental HIV/AIDS surveillance resources to expand current disease reporting regulations to require the reporting by public and private laboratories of all CD4+ T-lymphocyte test results and HIV viral load detection test results, to implement laboratory reporting of these results, and import laboratory data in eHARS. All requested funds will be allocated to MDPH's current IT consultant, Strategic Solutions Group, LIC (SSG), with in-kind support from existing Bureau of Infectious Disease (BID) staff and MDPH legal counsel.

The MDPH Office of Integrated Surveillance and Informatics Services (ISIS) within BID oversees surveillance and informatics activities to meet the data needs of the Divisions of Epidemiology and Immunization, STD Prevention and HIV/AIDS Surveillance, TB Prevention and Control, the Refugee and Immigrant Health Program and local boards of health. ISIS enhances and optimizes the collection and distribution of infectious disease surveillance data, and promotes standards-based electronic reporting of notifiable disease data by hospital laboratories, electronic health records, and other public health partners.

The MDPH Bureau of Laboratory Sciences (BLS) Informatics Office supports critical public health laboratory functions, including evaluation and implementation of new diagnostic testing methods, development of IT capacity to respond to new public health events and emergencies,

and enhancement of communications and data transfer between the state laboratory and its partners. Each BLS laboratory program works closely with its corresponding BID disease prevention program on joint surveillance projects, investigations of outbreaks and clinical cases, and other collaborative programmatic initiatives.

As a result of the strong collaboration between the BID and BLS, the Bureaus jointly developed the Electronic Laboratory Communication and Reporting (ELR) system to support the electronic exchange of information between public health agencies and its clinical partners, including hospitals, laboratories, providers and electronic health records. ELR was deployed in October 2004. It is a secure web-based system that is utilized by both BLS and BID. The BLS component of ELR provides laboratories and other health care partners with ability to receive test reports electronically. The system also serves as a single point of entry for Massachusetts hospitals, clinics and other health care providers to order tests and receive results electronically in HL7 format, search, view and print patient test reports, individually or by batch, and view the status of test orders.

The BID component of ELR allows hospitals and clinical laboratories to send data electronically on all reportable conditions to the MDPH BID. This includes laboratory results and clinical data held in electronic health records (EHR). Laboratory tests indicative of HIV infection are segregated from other laboratory results (per state regulation) and transmitted directly to the HIV/AIDS Surveillance Program to inform disease investigation by HIV/AIDS surveillance epidemiologists.

MDPH plans to initiate the expansion of ELR capacity to receive and triage full-range CD4+ T-lymphocyte test results and HIV viral load detection test results. Reporting laboratories are already capable of securely transmitting these results via ELR, but currently either strip their laboratory reporting of these non-required data elements or these elements are not utilized by the HIV/AIDS Surveillance Program. Expanding the capacity of ELR to accept and route these results will not prove a burden to reporting laboratories, but must be expressly required by state health regulation. Further, MDPH plans to create appropriate electronic routing of these test results to the HIV/AIDS Surveillance Program and translate them into eHARS-compliant code for further epidemiologic investigation.

Amended state disease reporting regulatory language requiring the laboratory reporting of will be proposed by BID in conjunction with MDPH legal counsel to the Massachusetts Public Health Council, the state health regulatory authority. Following the PHC's initial review of this proposed regulatory language, formal testimony and other input will be solicited via a public hearing process, and appropriate revisions made to the language, which will be presented back to the PHC for final promulgation.

Capacity

The working collaboration between BID, BLS, and the MDPH legal office have successfully implemented electronic laboratory reporting of data relevant to over 80 reportable diseases and maintains a state-of-the-art web-based disease surveillance system, the Massachusetts Virtual Epidemiologic Network (MAVEN) for managing laboratory reports, case reports, case management data, and other relevant information that automatically triages and routes these data for notifications and disease investigations by state and local health authorities, replacing paper-based legacy systems. The state Executive Office of Health and Human Services Information Technology Department (ITD) provides consolidated IT support and procurement capacity, and allocates its considerable technical capacity in accordance with

demonstrated need over and above the resource base of individual programs. BID's own ISIS and IT staff capacity has a proven track record of evolving burdensome paper-based legacy laboratory and epidemiologic systems into streamlined, efficient electronic systems, and have already migrated the majority of BID's component Divisions onto MAVEN and ELR. Similary, the HIV/AIDS Surveillance Program has fully implemented eHARS in a timely manner has been utilizing eHARS for disease investigation and reporting to CDC for over a year. The addition of electronic CD4+ T-lymphocyte and viral load test reporting is a relatively minor technical addition to the current resident systems, requiring primarily the configuration of existing software and translation code to accommodate this change. SSG is a long-term contractor of BID which is fully versed in the architecture of ELR and MAVEN and routinely accommodates changes to the program requirements of ISIS and BID's Divisions.

The BID Office of HIV/AIDS and the HIV/AIDS Surveillance Program have convened the HIV Surveillance Implementation Team, an external advisory group consisting of providers, HIV+ consumers, legal advocates, MDPH legal counsel, and community-based organization representatives since 1997 to guide MDPH in the initial implementation of HIV surveillance and the subsequent implementation of name-based reporting of HIV infection. In 2006, the HIV Surveillance Implementation Team authorized the amendment of state regulations permitting name-based HIV reporting and electronic reporting of HIV test results, and in 2010 authorized MDPH to pursue regulatory change to require full-range CD4+ and viral load laboratory reporting. The Public Health Council has consistently accepted the Team's recommendations regarding HIV surveillance policy and regulatory frameworks, and is likely to move quickly on these recommendations as well.

Proposed Objectives and Activities

Objective 1. CD4+ T-lymphocyte and HIV viral load detection test results will be required to be reported by public and private laboratories via ELR by June 30, 2011

Activities:
1. New disease reporting regulatory language will be drafted in consultation with state HIV Surveillance Implementation Team and MDPH legal counsel
2. Initial presentation of revised regulations to Public Health Council by November 30, 2011
3. Public comment period completed and public testimony on revised reporting regulation completed by January 31, 2011
4. Final promulgation of regulation will be voted on by Public Health Council by March 30, 2011
5. Revised regulations will take effect by June 30, 2011

Objective 2. Expand current ELR technical capacity to accept and appropriately route all CD4 and viral load test results by June 30, 2011

Activities:
1. Amend contract with SSG and fully encumber supplemental resources by September 30, 2010 to reconfigure ELR to accept and route all CD4 and viral load test results
2. SSG in consultation with ISIS, BID IT services staff, and staff of the HIV/AIDS Surveillance Program will complete the configuration of ELR by April 30, 2011
3. SSG and MDPH will complete quality testing of reconfigured ELR with dummy data by May 31, 2011

4. SSG and MDPH will pilot ELR with up to five reporting laboratories by June 15, 2011
5. CD4 and viral load reporting regulations will be in effect as of June 30, 2011 and statewide collection of these test results via ELR will begin

Objective 3. ELR will be reconfigured to translate received CD4 and viral load test results into eHARS by June 30, 2011

Activities:
1. Amend contract with SSG and fully encumber supplemental resources by September 30, 2010 to map native test reporting codes onto eHARS fields
2. SSG in consultation with ISIS, BID IT services staff, and staff of the HIV/AIDS Surveillance Program will complete the configuration of ELR by April 30, 2011
3. SSG and MDPH will complete test mapping function with dummy data by May 31, 2011
4. MDPH will begin entering real-time CD4 and viral load reports into eHARS by June 15, 2011

Timeline

All relevant timelines are cited in detail under Proposed Objectives and Activitites, including full regulatory implementation by June 30, 2011 and full reconfiguration of ELR to accept CD4 and viral load test results and map them onto e HARS fields by June 30, 2011.

Performance Measures

1. Needed regulatory change to require CD4 and viral load reporting will have been completed and in effect by June 30, 2011
2. No fewer than 50% of currently reporting laboratories will be reporting all CD4 and viral load test results by June 30, 2011
3. ELR system will be capable of accepting all CD4 and viral load reports by June 30, 2011
4. All reported CD4 and viral load test results will be successfully entered into eHARS by June 30, 2011

Assessment of attainment of these performance measures will be the joint responsibility of ISIS and HIV/AIDS Surveillance Program staff, and reported quarterly to Kevin Cranston, Director, Bureau of Infectious Disease.

Staffing

Primary oversight of this plan will be the responsi bility of James Murphy, MPH, Director of STD and HIV/AIDS Surveillance, consistent with HIV Surveillance cooperative agreement Additional technical support will be provided by Gillian Haney, MPH, Director of Integrated Surveillance and Informatics Services and Doreen Corban, Director of Information Technology and Informatics. Contracting processes will be overseen by Ceci Dunn, MPA, Director of Operations. Regulatory processes will be overseen by Kevin Cranston, MDiv, Director of the Bureau of Infectious Disease and Thera Meehan, MPH, MSW, Director of Policy and Planning, in consultation with Donna Levin, JD, Chief Legal Counsel. Public Health Council processes will be overseen by John Auerbach, MBA, Commissioner of Public Health.